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510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
MicroFrance® Wormald Vascular Clamps

510(k) Owner:	Medtronic Xomed, Inc 6743 Southpoint Drive North Jacksonville, Florida 32216-0980 USA 904-296-9600 904-296-2386 (FAX)
Contact Person:	Marsha Seetaram Regulatory Affairs Specialist Medtronic Xomed, Inc
Date Prepared:	September 9, 2011
Trade Name:	MicroFrance® Wormald Vascular Clamp
Common Name:	Vascular clamp
Classification Name:	Vascular clamp 21CFR 870.4450, Pro Code DXC, Class II
Predicate Device:	Wexler Vascular Clamp Series K110148 (Cleared 04/19/2011)
Device Description:	MicroFrance® Wormald Vascular Clamps enable a surgeon to suture the vessel defect, allowing the clamps to be released and therefore flow to be maintained. The stainless steel clamps are rotatable, allowing for proper orientation of the jaw tip as well as the handle. The device functions by clamping the jaw around the vessel to isolate the operative area. The degree of closure is adjusted by a ratcheting handle.
Statement of Intended Use:	MicroFrance® Wormald Vascular Clamps are indicated for use for temporary or partial occlusion of blood vessels during surgical procedures.
Conclusion from Data:	The data provided in this 510(k) Notification demonstrates that the proposed MicroFrance® Wormald Vascular Clamps are substantially equivalent to the predicate device since it has similar indications for use, principles of operation, materials and device design. The MicroFrance® Wormald Vascular Clamps are as safe, as effective, and performs as well as the predicate device.

Substantial Equivalence

The MicroFrance® Wormald Vascular Clamps have similar indications for use, principles of operation, materials and device design as the predicate device; Wexler Vascular Clamp Series [Table 1]. FDA originally cleared the predicate device under K110148 on April 19, 2011. K110148 510(k) summary is included in Appendix I.

Table 1: Comparison to Legally Marketed Device

Feature	MicroFrance® Wormald Vascular Clamps	Wexler Vascular Clamp Series
Manufacturer	Medtronic Xomed Instrumentation	Wexler Surgical Supplies, Inc.
510k Clearance	Subject of submission	K110148
Procode & Class	DXC and Class II	DXC and Class II
Intended Use	MicroFrance® Wormald Vascular Clamps are indicated for use for temporary or partial occlusion of blood vessels during surgical procedures.	The Wexler Vascular Clamp Series is indicated for use for temporary or partial occlusion of blood vessels during surgical procedures.
Various sizes, configurations	Yes	Yes
Principle of Operation	Clamp jaw applied around the vessel to isolate the operative area. The degree of closure is adjusted by a ratcheting handle.	Clamp jaw applied around the vessel to isolate the operative area. The degree of closure is adjusted by a ratcheting handle.
Design	Variety of jaw tips and orientations, ratchet lock on handle, ring handle, integrated flush port, rotatable shaft	Variety of jaw tips and orientations, ratchet lock on handle, ring handle
Material	Stainless Steel	Stainless Steel or Titanium
Sterility	Non-sterile	Non-sterile
Reusable	Yes	Yes

Summary of Non-Clinical Testing

Bench testing provided evidence that the proposed MicroFrance® Wormald Vascular Clamps performs according to specifications. The ratchet mechanism on each device allows the surgeon to apply varying degrees of pressure on the vessel. The nature of the tests comprised of three sections for each instrument type. It tested rotation, opening and closure of the jaws as well as testing of the clamps and jaw plating to ensure consistency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 20 2012

Medtronic USA, Inc.
c/o Marsha Seetaram
6743 Southpoint Dr. N.
Jacksonville, FL 32216-0980

Re: K112662
Trade Name: MicroFrance Wormald Vascular Clamp
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: December 15, 2011
Received: December 16, 2011

Dear Ms. Seetaram:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M A Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K112662

Device Name: MicroFrance® Wormald Vascular Clamps

Indications for Use: MicroFrance® Wormald Vascular Clamps are indicated for use for temporary or partial occlusion of blood vessels during surgical procedures.

Prescription Use ___X___ AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Kilcher

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112662